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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,278	04/21/2005	Gabrio Roncucci	M1100.70002US00	8497
23628	7590	03/06/2009	EXAMINER	
WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			WARD, PAUL V	
		ART UNIT	PAPER NUMBER	
		1624		
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		03/06/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,278	RONCUCCI ET AL.	
	Examiner	Art Unit	
	PAUL V. WARD	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 September 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10, 15, 16 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) 15, 16, 21 and 22 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10, 19, 20, 23 and 24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/19/05 & 4/21/05</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, claims 1-10, 19-20 and 23-24, in the reply filed on December 16, 2008 is acknowledged. The traversal is on the ground(s) that claim 23 should rightfully belong in Group III.

Applicant's argument is found persuasive and claim 23 will be examined along with Group III.

Groups I-II and IV are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement, and reserved the right to file a divisional application to the non-elected subject matter.

An action on the merits on claims 1-10, 19-20 and 23-24 is contained herein.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the term substituted. In the absence of the specific moieties intended to effectuate modification by "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claims in which it appears indefinite in all occurrences wherein applicant fails to articulate by

chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

2. The term "possibly", in claim 1, is a relative term, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
3. Claims 1-2 define variables (where applicable) as heterocycle/heterocyclic. The terms are indefinite since the specification does not define the ring size, heteroatom, number and nature of substituents, and the exact point of contact with the atom(s) for the substituents. Correction is required.
4. Claims 2-10 are rejected because they are dependent claims dependent on a rejected independent claim.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 19-20 and 23-24 are directed to a method of sterilizing wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases. The terms are interpreted to include any and all forms of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases. In light of this, it can be asserted that in

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spite of the vast expenditure of human and capital resources in recent years, no one drug has been found which is effective in treating all types of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases. In re Hokum, 226 USPQ 353 (ComrPats 1985).

The determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”.

These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claims is seen to encompass methods for treating wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases by administering to a patient in need of such treatment a therapeutically effective amount of the compound claim. Applicant

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failed to exactly define what types of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases are treated. Thus, the claims are extremely broad.

The nature of the invention

The nature of the invention is the treatment of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases through the use of the claimed compound and derivatives thereof. Currently, there are no known agents that treat these diseases all inclusively.

The level of predictability in the art

The treatment of wounds and viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases is highly unpredictable. It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved,” and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The amount of direction provided by the inventor.

The applicant has not demonstrated sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or reference to the same in the prior art to provide a skilled artisan with sufficient guidance to practice the instant treatment of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases claimed. Further, the applicant discloses that an effective amount of the compound will be administered without

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providing any direction other than that the compounds of the invention have a high therapeutic index and follows this with a definition readily found in a basic pharmacology textbook. It should be noted that the therapeutic index of a drug in humans is almost never known and is only determined through clinical experience.

The existence of working examples.

There is not seen in the disclosure, sufficient evidence to support Applicant's claims of treating wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases. A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 27 USPQ2d 1510 (CAFC). The disclosure does not demonstrate sufficient evidence to support the applicant's claim to the treatment and methods in inhibition. There are not sufficient working examples or data from references of the prior art to provide a nexus between those examples and a method of treating wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases with the claimed compound.

The level of one of ordinary skill.

The level of skill is that of one with a doctoral understanding of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological disease therapeutics. Applicant's data is not convincing as to make the

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production and use of pharmaceutical compositions comprising the recited compounds feasible without undue, un-predictable experimentation.

The quantity of experimentation.

A great deal of experimentation is required. In order for there to be a method of treating wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases generally, as claimed by the applicant, it would be necessary to show that a vast range of different types of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases. Furthermore, direction, in the form of examples, must be shown to determine what an effective dose may be. The references submitted do not demonstrate this. Therefore, one of ordinary skill in the art would require a significant amount of experimentation in order to determine the effective dosage to treat the multitudes of different types of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases with the claimed compound individually or in combination with other therapeutic agents.

Thus, it can be safely concluded that the instant case fails to provide an enabling disclosure for the treatment of wounds and treating viral, fungal, bacterial diseases characterized by cellular hyperproliferation and dermatological diseases.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

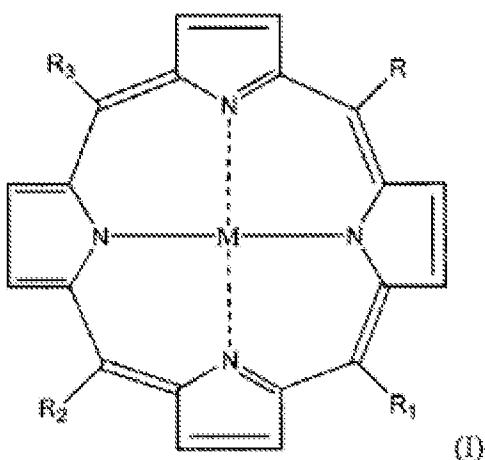
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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (Liquid Crystals' 2000).

Applicant teaches porphyrin compounds with a general formula I:

Compounds of general formula (I)



wherein all the variables are as defined in the claim.

Li discloses porphyrin compounds, which share the same formulaic compounds. (See Figure 2). The compounds in the said patent has the same structure, which includes M as Zn, R¹ as a H and a group of formula III of applicant's claim, R as formula II of applicant's claim, and R² and R³ as equal or different from each other, are selected from between R and R¹, and falls within the range of Applicant's porphyrin compounds. (See pages 551-552). Since Li teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

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7. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito et al. (Chem. Soc. Of Japan' 2001).

Ito discloses porphyrin compounds, which share the same formulaic compounds. (See Figure 1). The compounds in the said patent has the same structure, which includes M as Zn, R¹ as a H and a group of formula III of applicant's claim, R as formula II of applicant's claim, and R² and R³ as equal or different from each other, are selected from between R and R¹, and falls within the range of Applicant's porphyrin compounds. (See pages 657-658). Since Ito teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (Liquid Crystals' 2000).

Claim 1 is drawn to an optical recording material with a porphyrin core in which the moieties on the porphyrin core are substituted by variables represented by R and R₁-R₃, which are represented by formula II and formula III, and a metal component represented by the variable M which is represented by two hydrogens, a divalent, a trivalent or a tetravalent metal group.

DETERMINING THE SCOPE AND CONTENT OF THE PRIOR ART

Li teaches a compound with a porphyrin core which corresponds in structure with the instantly claimed compound of formula I. The moieties substituted by variables of said prior art core are substituted by variables represented by R and R₁-R₄ which are independently represented by formulae II and III of applicant's claim 1, containing moiety and a metal component represented by variable M which is represented by two hydrogens, a divalent, a trivalent or a tetravalent metal group

ASCERTAINING THE DIFFERENCES BETWEEN THE PRIOR ART AND THE CLAIMS AT ISSUE

The instant claims differ from the reference by reciting different carbon ranges for the overlapping moieties attached to the core of the compound through the porphyrin core.

CONSIDERING OBJECTIVE EVIDENCE PRESENT REGARDING OBVIOUSNESS

The prior art Chinese reference clearly discloses the class of compounds instantly claimed, which are porphyrin compounds, are recognized in the art by their correlative core. The variable substitution to the core of the prior art's compound and

the compound instantly claimed overlap so substantially that it would require little more than routine skill in the art to select moieties which would allow the skilled artisan to arrive at applicant's instantly claimed species.

RESOLVING THE LEVEL OF SKILL IN THE ART

It would have been obvious to one having ordinary skill in this art at the time the invention was made to substitute a porphyrin core with at least one moiety containing group and with the groups set forth in the prior art as applicant has done with the above cited reference before them. The prior art patent provides sufficient motivation to include the porphyrin compounds of the prior art and those rendered obvious in the instant application.

Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

9. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (Chem. Soc. Of Japan' 2001).

Claim 1 is drawn to an optical recording material with a porphyrin core in which the moieties on the porphyrin care are substituted by variables represented by R and R₁-R₃, which are represented by formula II and formula III, and a metal component represented by the variable M which is represented by two hydrogens, a divalent, a trivalent or a tetravalent metal group.

DETERMINING THE SCOPE AND CONTENT OF THE PRIOR ART

Ito teaches a compound with a porphyrin core which corresponds in structure with the instantly claimed compound of formula I. The moieties substituted by variables

of said prior art core are substituted by variables represented by R and R₁-R₄ which are independently represented by formulae II and III of applicant's claim 1, containing moiety and a metal component represented by variable M which is represented by two hydrogens, a divalent, a trivalent or a tetravalent metal group

ASCERTAINING THE DIFFERENCES BETWEEN THE PRIOR ART AND THE CLAIMS AT ISSUE

The instant claims differ from the reference by reciting different carbon ranges for the overlapping moieties attached to the core of the compound through the porphyrin core.

CONSIDERING OBJECTIVE EVIDENCE PRESENT REGARDING OBVIOUSNESS

The prior art Japanese reference clearly discloses the class of compounds instantly claimed, which are porphyrin compounds, are recognized in the art by their correlative core. The variable substitution to the core of the prior art's compound and the compound instantly claimed overlap so substantially that it would require little more than routine skill in the art to select moieties which would allow the skilled artisan to arrive at applicant's instantly claimed species.

RESOLVING THE LEVEL OF SKILL IN THE ART

It would have been obvious to one having ordinary skill in this art at the time the invention was made to substitute a porphyrin core with at least one moiety containing group and with the groups set forth in the prior art as applicant has done with the above cited reference before them. The prior art patent provides sufficient motivation to include the porphyrin compounds of the prior art and those rendered obvious in the instant application.

Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

Conclusion

Claims 1-10, 19-20 and 23-24 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/PAUL V WARD/
Examiner, Art Unit 1624**

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**